Complete Summary

GUIDELINE TITLE

Trichomonas vaginalis infection. In: sexually transmitted infections: UK national screening and testing guidelines.

BIBLIOGRAPHIC SOURCE(S)

Mabey D, Ackers J, Adu-Sarkodie Y. Trichomonas vaginalis infection. In: Ross J, Ison C, Carder C, Lewis D, Mercey D, Young H. Sexually transmitted infections: UK national screening and testing guidelines. London (UK): British Association for Sexual Health and HIV (BASHH); 2006 Aug. p. 63-7. [34 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

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SCOPE

DISEASE/CONDITION(S)

Trichomoniasis (*Trichomonas vaginalis* infection)

GUIDELINE CATEGORY

Diagnosis Screening

CLINICAL SPECIALTY

Family Practice Infectious Diseases Internal Medicine Obstetrics and Gynecology Urology

INTENDED USERS

Advanced Practice Nurses Clinical Laboratory Personnel Nurses Physician Assistants Physicians Public Health Departments

GUIDELINE OBJECTIVE(S)

- To provide advice on what tests for *Trichomonas vaginalis* are most appropriate in a United Kingdom (UK) genitourinary (GU) clinic setting (excluding human immunodeficiency virus [HIV]-infected patients)
- To provide a basis for audit
- To support clinics when bidding for additional resources to meet national standards

TARGET POPULATION

Individuals in the United Kingdom presenting with suspected *Trichomonas* vaginalis infection

INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Microscopy of a wet mount preparation
- 2. Culture (Diamond's TYM medium recommended)
- 3. Latex agglutination test
- 4. Polymerase chain reaction (PCR) testing for *Trichomonas vaginalis* deoxyribonucleic acid (DNA) (not available in the United Kingdom)
- 5. Testing sites (vaginal swabs, urethral swabs, first catch urine)
- 6. Follow-up testing for cure

MAJOR OUTCOMES CONSIDERED

Sensitivity and specificity of test methods

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Hand-searches of Published Literature (Secondary Sources) Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A PubMed search of the English language literature was conducted up to December 2004, using the key words *Trichomonas vaginalis* and trichomoniasis. Personal libraries and the abstracts of recent meetings of the International Society for Sexually Transmitted Diseases (STD) Research were also scrutinised.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

Ia: Evidence obtained from meta-analysis of randomised controlled trials

Ib: Evidence obtained from at least one randomised controlled trial

IIa: Evidence obtained from at least one well designed controlled study without randomisation

IIb: Evidence obtained from at least one other type of well designed quasi-experimental study

III: Evidence obtained from well designed non-experimental descriptive studies

IV: Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The guidelines have been developed following the methodological framework of the Appraisal of Guidelines Research and Evaluation instrument (AGREE - adapted as described in Int J STD and AIDS 2004 15. 297 - 298, 299 - 305).

The extent to which the guideline represents the views of intended users has been addressed primarily by the authorship coming from the multidisciplinary membership of the Bacterial Special Interest Group (BSIG). As practising clinicians the authors were able to draw on their experience of applying the tests to symptomatic and asymptomatic patients but it was not feasible to obtain formal input from representative patients.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grading of Recommendations:

- **A** (Evidence at level Ia or Ib)
- **B** (Evidence at level IIa, IIb, III)
- C (Evidence at level IV)

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

After drafting, other health care professionals and professional bodies in genitourinary (GU) medicine were asked to comment, the draft guidelines posted on the British Association for Sexual Health and HIV (BASHH) website for 3 months, and all comments reviewed before final publication.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions for the level of evidence (I-IV) and grade of recommendation (A-C) are provided at the end of the "Major Recommendations" field.

Recommended Tests

Microscopy of a wet mount preparation is the most commonly used diagnostic test for *Trichomonas vaginalis* (*T. vaginalis*) infection. Characteristic motile flagellated protozoa are readily seen. Microscopy for *T. vaginalis* should be performed as

soon as possible after the sample is taken as motility diminishes with time. Wet mount microscopy is approximately 70% sensitive compared to culture in women, and significantly less sensitive in men. At present, culture techniques are still regarded as the most sensitive and specific; they provide the "gold standard" against which other methods are judged. (Evidence Level III, Grade of Recommendation B)

Culture media vary in efficiency but Diamond's TYM medium (sometimes with minor modifications) is amongst the best. Most tubes will be positive within 48 hours but should be kept for 7 to 10 days before being finally discarded. A very convenient, but expensive, way of culturing specimens is the InPouch® system which appears to be at least as sensitive as conventional tubed media. (Evidence Level III, Grade of Recommendation B)

A **latex agglutination test** which detects *T. vaginalis* antigen was described some years ago. This rapid and simple bedside test, which does not require electricity or special equipment, has been reported to have sensitivities of 95% and 98.8 % and specificities of 99% and 92.1% compared to culture for the diagnosis of *T. vaginalis* infection in women. This diagnostic test is available in kit form (TVlatex; Kalon Biological Ltd, Ash Vale, GU12 5QJ, UK). **(Evidence Level III, Grade of Recommendation B)**

More recently, several protocols have been described for the detection of *T. vaginalis* DNA in clinical samples using the polymerase chain reaction (PCR). Some of these assays appear to be more sensitive than culture although, as with PCR assays for *Chlamydia trachomatis* infection when they were first introduced, it is not immediately apparent whether samples positive by polymerase chain reaction (PCR) and negative by culture represent false negatives by culture, or false positives by PCR. No PCR assay for *T. vaginalis* is currently on the market in the United Kingdom (UK). **(Evidence Level III, Grade of Recommendation B)**

Who Should Be Tested?

Until recently, *T. vaginalis* has not been considered an important pathogen since, unlike other sexually transmitted infection (STIs), it was not believed to cause serious sequelae. Its importance is now being reassessed in the light of recent evidence that it is associated with adverse pregnancy outcome and facilitates the sexual transmission of HIV infection. However further research is needed to confirm these associations and to prove that the association is causal. Moreover recent trials have found that treatment of *T. vaginalis* infection in pregnancy does not improve pregnancy outcome, and may be harmful. **Screening of asymptomatic individuals for** *T. vaginalis* **infection is therefore not currently recommended. (Evidence Levels I and II, Grade of Recommendation A)**

Women attending clinics with a complaint of vaginal discharge should be tested for *T. vaginalis* infection. (Evidence Level III, Grade of Recommendation B) It is generally recommended that sexual partners of infected women should be treated epidemiologically. (Evidence Level 1b, Grade of Recommendation A) Testing of male partners could in theory lead to further contact tracing in those who test positive. (Evidence Level IV, Grade of Recommendation C)

Men with urethral symptoms which persist after infection with *Neisseria* gonorrhoeae, *Chlamydia trachomatis* and *Mycoplasma genitalium* have been excluded or treated should be tested for *T. vaginalis* infection. (Evidence Level III, Grade of Recommendation B)

Test of cure is only recommended in those whose symptoms persist after treatment. (Evidence Level IV, Grade of Recommendation C)

Recommended Sites for Testing

In women, a swab should be taken from the posterior fornix at the time of speculum examination. (Evidence Level III, Grade of Recommendation B). Self-administered vaginal swabs have been used in many recent studies, and are likely to give equivalent results. (Evidence Level III, Grade of Recommendation B) First catch urine (FCU) specimens, with or without centrifugation, have also been tested in women, but the sensitivity is less than that achieved with vaginal swabs. (Evidence Level III, Grade of Recommendation B)

In men, urethral swabs or FCU samples are recommended. The sensitivity of FCU can be improved by testing a cell pellet after centrifugation. Sensitivity can be improved by testing both a swab and a FCU. (Evidence Level III, Grade of Recommendation B). Swabs from the sub-preputial space may also be tested, but this method of specimen collection has not been well validated. (Evidence Level IV, Grade of Recommendation C)

Definitions:

Levels of Evidence

Ia: Evidence obtained from meta-analysis of randomised controlled trials

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Grading of Recommendations

A (Evidence at level Ia or Ib)

B (Evidence at level IIa, IIb, III)

C (Evidence at level IV)

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for selected recommendations (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate screening of *Trichomonas vaginalis* infection

POTENTIAL HARMS

Not stated

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006 Aug

GUIDELINE DEVELOPER(S)

British Association for Sexual Health and HIV - Medical Specialty Society

SOURCE(S) OF FUNDING

No specific or external funding was sought or provided in the development of this guideline.

GUIDELINE COMMITTEE

Screening Guidelines Steering Committee Clinical Effectiveness Group (CEG)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Authors: David Mabey, Department of Infectious & Tropical Diseases, London School of Hygiene & Tropical Medicine; John Ackers, Department of Infectious & Tropical Diseases, London School of Hygiene & Tropical Medicine; Yaw Adu-Sarkodie, Department of Infectious & Tropical Diseases, London School of Hygiene & Tropical Medicine

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Conflict of interest; None declared.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from <u>British</u> Association for Sexual Health and HIV Web Site.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

 Specifications for the development of UK guidelines on the management of sexually transmitted infections (STIs) and closely related conditions 2005.
 London (UK): British Association of Sexual Health and HIV (BASHH); 2005. 14
 p. Electronic copies: Available in Portable Document Format (PDF) from the British Association for Sexual Health and HIV Web site.

Additionally, auditable outcome measures can be found in the <u>original guideline</u> document.

PATIENT RESOURCES

None available

NGC STATUS

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